U. S. Department of Energy

Environmental Management Consolidated Audit Program

Module 9

Checklist for Industrial Hygiene General Laboratory Practices Quality Management

Audit ID: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
9.1	**Quality Assurance Documents**		
9.1.1	The laboratory has developed a Laboratory Quality Assurance Plan (QAP) consistent with DOE Order 414.1 and SW-846 that is issued and maintained as a controlled document. (*ICPT SOW Attachments B/C, Criterion 1, Program*) *(SW-846, Chapter 1, Section 2.0)*		
9.1.2	The QAP defines the laboratory's policies and its commitment to: • ethical standards; • client confidentially; • good laboratory practices; and, • client service. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7*)		
9.1.3	The QAP includes a listing of certifications and accreditations or a reference to the location of such a list if not part of the QAP. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7*)		

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9.1.4	The QAP describes the: • organizational structure; • functional responsibilities; • levels of authority; and, • interfaces for those managing, performing and assessing work. (*AIHA Laboratory Quality Assurance Pollicies Sect. 2.7.2*)		
9.1.5	The QAP is accessible to all laboratory personnel and they are aware of its location. (AIHA Laboratory Quality Assurance Policies Sect. 2.7.1)		
9.1.6	The QAP includes an organizational chart showing that QA personnel: • operate independently from line management • are not directly involved with cost, schedule or production functional areas; and, • report directly to the highest level of laboratory management. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7.2 & 2.5.2*)		

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9.1.7	The QAP is reviewed and approved by management at least annually. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.1)*		
9.2	**Quality Assurance Management**		
9.2.1	General Quality Assurance responsibilities include: • oversight of corrective actions; • oversight of PE analysis; • report to management; • internal audits; and, • review of SOWs and SOPs. (*AIHA Laboratory Quality Assurance Policies Sect. 2.5.2*)		

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9.2.2	A Quality Assurance Officer has been designated in writing who is empowered to: • stop unsatisfactory work; • prevent reporting results from an out of control measurement system; • initiate and monitor corrective action procedures; and, • revise, control and distribute the QAP. (*AIHA Laboratory Quality Assurance Policies Sect. 2.5.2*)		
9.3	**Performance Evaluation Programs**		
9.3.1	The laboratory demonstrates successful participation in the American Industrial Hygiene Association Proficiency Analytical testing (PAT) program. *(AIHA Laboratory Quality Assurance Policies Sect B.6)*		
9.3.2	The laboratory documents the root cause and corrective action for failed PE samples. (*AHIA Laboratory Quality Assurance Policies Sect. B.6.1*)		

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9.3.3	If the laboratory analyzes for lead, it demonstrates successful participation in the AIHA Environmental Lead Proficiency Testing (ELPAT). *(AIHA Laboratory Quality Assurance Policies Sect. C.7)*		
9.3.4	If the laboratory analyzes for bulk asbestos, it demonstrates successful participation in the National Voluntary Laboratory Accreditation Program (NVLAP) Bulk Asbestos Accreditation Program or the AIHA Bulk Asbestos Program. *(AIHA Laboratory Quality Assurance Policies Sect B.6)*		
9.4	**Personnel Training and Qualification**		
9.4.1	A regularly reviewed process is implemented to control purchased items and services, including the following elements: • applicable technical and administrative requirements; • process for selecting and qualifying subcontractors; • process to ensure that qualified subcontractors continue to provide acceptable products/services; • process for accepting purchased items/services; • process for receiving and maintaining procurement records; and, • documenting nonconforming items/services.		

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	(AIHA Laboratory Quality Assurance Policies Sect. 2.3 and Sect. 2.7.8)		
9.5	**Personnel Training and Qualification**		
9.5.1	The laboratory organization possesses well-defined and documented roles and responsibilities for each position. (*AIHA Laboratory Quality Assurance Policies Sect. 2.5*)		
9.5.2	The laboratory maintains records of indoctrination and training in the form of: • attendance sheets; • training logs; • personnel training records; and, • a description of the training and indoctrination. (*AIHA Laboratory Quality Assurance Policies Sect. 2.5.6)*		

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9.5.3	Documentation is maintained indicating training in: • technical skills; • laboratory analytical methods; • QC procedures; • safety policies; • waste management practices; and, • radiation worker training. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7.4)*		
9.5.4	The laboratory has a written internal analyst proficiency evaluation policy that provides a means to gauge and document the continuing competence of experienced individuals, as well as specifying additional training and documentation practices applicable to all personnel. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.4)*		
9.5.5	Management and supervisory personnel possess a BS or BA in applicable physical or biological science and 5 years directly related experience *(AIHA Laboratory Quality Assurance Policies Sect. 2.5.1)*		

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9.5.6	Written documentation is available to support qualifications of staff consisting of a listing personnel, their assignments responsibilities, degrees of education and years of applicable experience. *(AIHA Laboratory Quality Assurance Policies Sect. 2.5.6)*		
9.5.7	All analysts and technicians have a minimum of 30 calendar days of hands-on-experience conducting analyses in an industrial hygiene laboratory before initiation of independent work on customer samples. *(AIHA Laboratory Quality Assurance Policies Sect. B.3.2.3)*		
9.6	**Quality Control Systems**		
9.6.1	The laboratory has established a system to identify, document, correct, and prevent quality problems. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7.10)*		
9.6.2	The laboratory has established a “Non-Conformance System” to identify problems, out-of-control events and issues that are not part of scheduled assessments.		

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	(AIHA Laboratory Quality Assurance Policies Sect. 2.7.10.8)		
9.6.3	At least quarterly, the QA Manager provides reports to laboratory management regarding quality assurance problems and corrective and preventive actions. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.15)*		
9.6.4	A corrective action process has been implemented which determines: • events leading to the adverse condition; • technical activities associated with the problem; • generic implications of the problem; • extent to which similar problems have occurred; • assignment of personnel to corrective action; • documentation of corrective action plan; • effectiveness of corrective actions; • actions taken to preclude recurrence; • review of regulatory requirements; and, • client notification. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7.13)*		

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9.6.5	Written procedures are in place for the notification of affected organizations regarding nonconforming items. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7.4)*		
9.6.6	The laboratory has a system that tracks corrective actions to completion. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.13)*		
9.7	**Documents and Records**		
9.7.1	Laboratory activities affecting quality are defined in documented instructions or procedures which are: • distributed in a controlled manner; • periodically reviewed and updated; • available to all laboratory personnel; and, • retained in the laboratory's archives. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7.16)*		

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9.7.2	The laboratory has established a minimum frequency for review of controlled documents and procedures. (*AIHA Laboratory Quality Assurance Policies Sect. 2.7.13)*		
9.7.3	Documents are retained for a minimum of five years. *(DOE Records Management Requirement)*		
9.7.4	Standard Operating Procedures are in place for (but not limited to) the following areas: • analytical tests; • sample tracking and COC (from receipt to disposition); • sample preparation (including subsampling); • sample storage and security; • proper sample disposition; • prevention of sample contamination; • facility security; • data reduction, verification, and reporting; • acceptance criteria (e.g., QC limits, calibrations, etc.); • document control; • data packages review prior to submittal; • shipment of deliverables; • records disposition; • preparation and traceability of standards; • catastrophic failure of a refrigerator, freezer unit;		

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	• glassware cleaning; • equipment maintenance; and, • qualification of personnel and training. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.16)*		
9.7.5	At a minimum the SOPs define, establish and implement the following: • identification of the test method; • applicable matrix or matrices; • detection limit; • scope and application, including components to be analyzed; • summary of the test method; • definitions; • interferences; • safety;		

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	• equipment and supplies; • reagents and standards; • sample collection, preservation, shipment, storage; • quality control; • calibration and standardization; • procedure; • calculations; • method performance; • pollution prevention; • data assessment and acceptance criteria for quality control measures; • corrective actions for out-of-control data; • contingencies for handling out-of-control or unacceptable data; • waste management; • references; and, • any tables, diagrams, flowcharts and validation data. (*NELAP 5.10.1.2*)		
9.7.6	A system is in place to ensure that quality records are legible, accurate, and complete, e.g., independent review or records, logbooks, etc. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.16)*		
9.7.7	Corrections to documents that will become quality records are made by drawing a single line through the error, initialing and dating the error, and justifying the correction		

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	(if not self-explanatory). *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.9.3)*		
9.7.8	The laboratory has a procedure delineating the records control system that includes: • specifications of items, data, and processes of which records are to be controlled; • requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements; • requirements and responsibilities for record transmittal distribution, change, retention, protection preservation, traceability, archival, retrieval, and disposal; • verification that records received are legible and are in agreement with the transmittal document; • requirements for access to and control of the files; • procedures for the control, and client confidentiality accountability of records removed from the storage location; • procedures for filing of supplemental information and disposing of superseded records; • storage of records in a manner approved by the organizations responsible for the records; • replacement, restoration, or substitution of lost or damaged records; and, • procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct data.		

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	(AIHA Laboratory Quality Assurance Policies Sect. 2.7.16 & 2.7.17)		
9.7.9	The laboratory has procedures in place to validate non-standardized methods, laboratory designed/developed methods, standardized methods used outside their intended range and amplifications of standardized methods to confirm that the methods are fit for the intended use. The procedures include: • scope; • description of the type of item to be tested or calibrated; • parameters or quantities to be determined; • apparatus, equipment, reference standards and reference materials required; • environmental conditions required and any stabilization period needed; • description of the procedure, including affixing identification marks, handling, transporting, storing and preparing of items, checks to be made before the work is started, checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use, method of recording the observations and results, any safety measures to be observed; • criteria and/or requirements for approval/rejection;		

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	• data to be recorded and method of analysis and presentation; • uncertainty or procedure for estimating uncertainty. (*ISO 17025 – 5.4.4 & 5.4.5 and OSHA Inorganic Method Evaluation Protocol and OSHA Organic Method Evaluation Protocol)*		
9.7.10	The laboratory has procedures for reviewing and documenting changes made to data after report preparation that ensure traceability of updates. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.17)*		
9.7.11	Records of data and other technical information are maintained in environmentally secure controlled access storage, which shall protect the records from unauthorized access or damage. Alternatively, the laboratory stores duplicate records at a different location. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.17.2)*		
9.8	**Work Process**		

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9.8.1	Annually or when there is a change in methodology or instrumentation, reporting limits are verified by a statistically valid MDL study. *(AIHA Laboratory Quality Assurance Policies Sect. B.4.3.3)*		
9.8.2	A Standard Operating Procedure is in place for reagent and deionized water production which includes (at a minimum): • preventative maintenance of water purification equipment; • control criteria; and • corrective action process for out-of-spec water. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.7)*		
9.8.3	The laboratory has a water system capable of meeting the ASTM specifications for "Type II" water. *(ASTM D1193).*		
9.8.4	The conductivity and/or resistivity of the water from the purification system is monitored daily and the results are recorded in a logbook. *(NIOSH Specific Methods)*		

Status Key: A = Acceptable, U = Unacceptable, NA = Not Applicable, F = Finding, O = Observation

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9.8.5	Sample glassware and containers are either designated as disposable or cleaned according to recommended procedures that are listed in the individual Analytical Master Specifications. *(NIOSH Specific Methods)*		
9.8.6	A copy of the laboratory-specific Standard Operating Procedure (SOP) for glassware is posted in the glassware cleaning area. The sample preparation areas is kept clean to avoid contamination or cross-contamination.		
9.8.7	A refrigerator storage blank is present for the storage of all volatile organic samples. Specific procedures for assessing the adequacy of these storage blank data and taking action for nonconforming conditions is established. The refrigerator storage blank is analyzed every 14 days when samples are being stored in the laboratory. The data from the analysis of the refrigerator storage blanks is available for review. *(ICPT SOW - Attachments B/C, Special QA Requirements, Section B.3)*		

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9.8.8	The laboratory maintains hard copy laboratory notebooks that detail: • sample bottle preparation and analytical work, including the analyses being performed; • samples being analyzed; • procedures used; • reading taken; • calculations performed; • analytical results; and, • any observations during analysis. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.16 and 2.7.17)*		
9.8.9	Standards and reference materials shall be stored separately from samples and standards protected in a controlled cabinet or refrigerator. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.7)*		
9.8.10	Reagent grade or higher purity chemicals are used. Reagents are checked prior to use and the supporting documentation of the checks shall be filed in a manner that can be easily retrieved. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.7)*		

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9.9	**Statistical Control Methods**		
9.9.1	The laboratory Quality Control manager or his/her designee periodically reviews control charts at a specified frequency for out of control conditions and initiates appropriate corrective action procedures. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.7)*		
9.9.2	Control methods are accessible to the individual performing the analyses, data reviewers, and the quality assurance staff. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.7)*		
9.10	**Internal Audit Procedures**		
9.10.1	The laboratory has established an internal audit program which includes: • independent assessments by technically qualified personnel; • maintenance of an audit schedule; • audit procedures; • standard formats for reporting findings to laboratory management; and, • methods for implementing and verifying corrective actions.		

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	(AIHA Laboratory Quality Assurance Policies Sect. 2.7.11)		
9.10.2	Personnel conducting independent assessments have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.11)*		
9.10.3	Assessment results are documented, reported to and reviewed by the level of management with authority to affect any necessary corrective actions. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.11)*		
9.11	**Sample Receiving**		

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9.11.1	The laboratory has procedures in place to address the following: • checking sample preservation (pH), • proper containers; • preserving samples when required; • notifying clients of shipping or sample anomalies; • checking holding times and notification of lab personnel of short holding times; • use of fume hoods for opening samples and shipping containers; and, • radiation screening of samples, lab notification and labeling requirements for radioactive samples. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.6)*		
9.11.2	Sample custodians document anomalies encountered in the sample receiving process. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.6)*		
9.12	**Sample Control and Building Security**		

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9.12.1	Physical or administrative controls exist to ensure that: • Chain of Custody (COC) is not broken during times that laboratory staff are present or not present, • visitor access is controlled by positive administrative controls and strict escort rules developed for all visitors; and, • the facility has controlled entrance and egress points. *(AIHA Laboratory Quality Assurance Policies Sect. 2.2 and sect. 2.7.6)*		
9.12.2	A sample receiving logbook or equivalent system is used to record the chronology of sample entry into the laboratory including time, date, customer, sample identification numbers, etc. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.6.1)*		
9.12.3	When the laboratory receives samples, an internal chain of custody procedure is initiated. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.6)*		

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9.12.4	Internal custody is maintained until final disposition or return of the sample to the client. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.6.5)*		
9.12.5	The laboratory maintains an indexed sample storage system that facilitates sample retrieval. *(AIHA Laboratory Quality Assurance Policies Sect. 2.7.6)*		
9.12.6	The laboratory has established, implemented and documented procedures to ensure the sample's radioactivity levels are consistent with the accompanying documentation and that Laboratory regulatory levels are not exceeded. *(ICPT SOW - Attachments B/C - special QA Requirements, Section G.5)*		
9.13	**Inspection and Acceptance Testing**		

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9.13.1	The laboratory maintains a current list of available (on hand) equipment types, models, and years and a general description of the facility. *(AIHA Laboratory Quality Assurance Policies Sect. 2.4)*		
9.13.2	A schedule of preventive maintenance activities is developed and the performance of preventive maintenance is documented. *(AIHA Laboratory Quality Assurance Policies Sect. 2.4)*		
9.13.3	Procedures are defined for ensuring that balances, refrigerators, ovens, and other laboratory equipment are accurate and that their performance is monitored and documented. *(AIHA Laboratory Quality Assurance Policies Sect. 2.4)*		
9.13.4	Balances are checked each day that they are used and are calibrated at least annually by an independent company or source. *(AIHA Laboratory Quality Assurance Policies Sect. 2.4)*		

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9.13.5	Refrigerator temperatures shall be monitored daily. *(AIHA Laboratory Quality Assurance Policies Sect. 2.4)*		
9.14	**Laboratory Accreditation**		
9.14.1	Laboratory is currently accredited by AIHA		
9.14.2	If laboratory analyzes for environmental lead, it possesses an ELLAP accreditation		